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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,594	01/05/2006	Alain Prochiantz	275010US0XPCT	1972

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EXAMINER	
MAKAR, KIMBERLY A	
ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
01/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,594	PROCHIANTZ ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to methods of making a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues.

Group II, claim(s) 7-9, drawn to a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues.

Group III, claim(s) 10-15, drawn to a method of introducing a cargo into a living cell in culture comprising contacting said living cell with a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention lacks novelty. Divida et al (WO 02/10201) listed in applicants IDS dated 09/19/05 teaches a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5

consecutive basic residues (see page 12-15, particularly page 12 lines 18-23, page 13 lines 25-30, page 15 lines 14-16, and page 25 and page 26 lines 24-30).

3. The technical feature of group I, drawn to methods of making a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues is distinct from the technical feature of group II, drawn to a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues. The composition of group II can be made using alternate methodologies, such as encoding the transduction domains and cargo in vitro and lysing the cells, and then isolating the assembled composition. Thus groups I and II are capable of supporting individual patents.

4. The technical feature of group I, drawn to methods of making a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues is distinct from the technical feature of group III, drawn to a method of introducing a cargo into a living cell in culture comprising contacting said living cell with a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues. The methodology of making the composition of group I is not required for using the composition in group III. Thus the methodologies between groups I and III are distinct methodologies, requiring different reagents, protocols and results. Thus groups I and III are capable of supporting individual patents.

5. The technical feature of group II, drawn to a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic residues, is distinct from the technical feature of group III, drawn to a method of introducing a cargo into a living cell in culture comprising contacting said living cell with a composition comprising a transducing peptide and a cargo, wherein the transducing peptide is not 16-30 amino acids residues in length comprising a hydrophobic domain containing 3 to 5 tryptophan residues and at least one Trp-Trp pair, alternating with glutamic acid and threonine residues, and a hydrophilic domain containing 4 or 5 consecutive basic

residues. The composition of group II can be used in alternate methodologies, such as in a method of introducing a cargo into a living cell in vivo by administering the transducing composition into the bloodstream of a mammal. Thus groups II and III are capable of supporting individual patents.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/12/29/07

Joe Woitach
SPE 1636